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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,929	11/19/2003	Rekha Bansal	NMT-8440	6425

26294 7590 04/15/2008

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
04/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/716,929	BANSAL, REKHA	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,6 and 22-44* is/are pending in the application.

4a) Of the above claim(s) *5,6 and 22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20071119 (2 docs)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4 and 7-21 have been canceled.

New claims 25-44 have been added.

Claims 5, 6 and 22-44 are currently pending.

Election/Restrictions

1. **Claims 5, 6 and 22-24 stand withdrawn from further consideration** pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 16, 2006. Please note that claim 22 is also withdrawn because it does not read upon the binding molecule of the elected invention.

Accordingly, **claims 25-44 are the subject of examination** in the present Office Action.

2. In view of Applicant's amendment, no outstanding grounds of rejection are maintained.

The following new grounds of rejection have been necessitated by Applicant's amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 25-27, 29-34, and 36-44 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/21559 (Musc Foundation for Research Development; N on form PTO-892, newly cited).

The '559 document discloses that Factor B is a component of the alternative complement pathway, is a B cell growth factor, stimulates mononuclear cell cytotoxicity, induces macrophage spreading, and solubilizes immune complexes (page 2, lines 2-5 in particular). The '559 document further discloses that Factor B is an important mediator of complement mediated disease (page 2, lines 19-23 in particular). The '559 document teaches treatment of subjects in need thereof with anti-Factor B antibodies (page 6, lines 13-20 in particular). The '559 document teaches the manufacture of monoclonal antibodies to Factor B [claims 27, 34] (pages 7, lines 5-10 in particular). The '559 teaches

intravenous injection of the anti-Factor B antibody to a subject, which is administration to the blood of the subject (page 7, lines 14-16 in particular). The '559 document teaches patients with complement-mediated immune diseases such as vasculitis, systemic lupus erythematosus, rheumatoid arthritis, myocardial infarction, ischemic/reperfusion injury, cerebrovascular accident, Alzheimer's, multiple sclerosis, cardiopulmonary bypass injury, vasculitis, post streptococcal glomerulonephritis, membranous glomerulonephritis as being among those suitable subjects in need thereof [claims 32, 39] (page 6, lines 1-11 in particular). The prior art teaching anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 28 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/21559 (Musc Foundation for Research Development; N on form PTO-892) as applied to claims 27 and 34 above, and further in view of Harlow et al. (Antibodies: A Laboratory Manual. [1988] pages 72-77, 92-97, 128-135, 141-157 and 628-631; U on form PTO-892).

The '559 document has been discussed supra.

The '559 document does not specifically teach antibody fragments.

Harlow teaches that any substance that can elicit a humoral response can be used to prepare mAbs and that mAbs are powerful reagents for the testing for the presence of a desired epitope. Harlow teaches methods for immunizing animals for the production of polyclonal and monoclonal antibodies (pages 72-77, 92-97, 128-135 and 141-157 in particular) as well as the types of antigens to which such antibodies can be made including proteins, peptides, and carbohydrates (any of which could qualify as a ligand,

depending on the receptor)(pages 153-154 in particular). Harlow further teaches that because antibodies may recognize small determinants they may be cross-reactive with similar epitopes on other molecules (page 24, last paragraph in particular) and that epitopes may be formed by linear epitopes within an amino acid sequence or to epitopes which are formed by determinants from different parts of a molecule which are brought together due to conformation of said molecule (page 25, first section in particular). Harlow further teaches the manufacture of Fab fragments of monoclonal antibodies (pages 628-631 in particular).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine these references to produce fragments of monoclonal antibodies to Factor B using the methods taught by Harlow. One would have been motivated, with a reasonable expectation of success, to combine these references because it is conventional in the art to produce fragments of monoclonal antibodies for *in vivo* use.

Information Disclosure Statement

5. A number of references cited on the PTO-1449 forms filed 11/19/2008 have been lined through and not considered because copies of the references were not provided. It is noted that a number of the provided documents were actually blank pages, which may explain the missing references.

It is further noted that all of the citations on form PTO-1449 list the complete reference. However, for the majority of references cited, only the abstract or summary obtained from an internet database or publisher website was provided. Accordingly, in those cases, ONLY the abstract was considered and the on form PTO-1449 has been duly marked to indicate this.

Conclusion

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH

shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571)272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D. /PV/
Patent Examiner
March 29, 2008

/David A Saunders/
Primary Examiner, Art Unit 1644